



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 2 2000

Food and Drug Administration
Rockville MD 20857

2725 '00 MAR -6 A9:45

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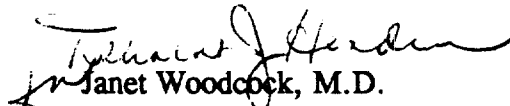
Re: Docket No. 99P-4053/CP/1

Dear Doctors Maher and Wurtman:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted to the Dockets Management Branch on September 13, 1999, and supplemented on November 9, November 16, and December 20, 1999. Your petition requests that the Agency amend required product labeling and the patient insert for the sympathomimetic amine phentermine (in all salt forms) to indicate that it inhibits the enzyme monoamine oxidase and should be classified as a monoamine oxidase inhibitor.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely yours,


Janet Woodcock, M.D.
Director

Center for Drug Evaluation and Research

99P-4053

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